K083446
Page 1 of 2

510(k) Summary

MAR 31 2009

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

General Information

Trade Name	***Cardiac Function Analysis*** ***Calcium Scoring***
Common Name	Picture Archiving and Communications System (PACS)
Classification Name	System, Image Processing, Radiological (21 CFR § 892.2050 - LLZ)

Applicant: **Ziosoft, Inc.**
1000 Bridge Parkway, Ste. 100
Redwood City, CA 94065
Tel 650-413-1300
Fax 650-596-7319

Contact: Richard Ball
Director, Regulatory and Quality Affairs

Intended Use

Cardiac Function Analysis

The Cardiac Function Analysis software option for use with Ziostation is intended for non-invasive post-processing of DICOM compliant cardiac CT images to semi-automatically calculate and display various functional parameters, such as left ventricular ejection fraction, end diastolic volume, end systolic volume, stroke volume, cardiac output, cardiac index, wall thickness, wall thickness ratio and regional wall motion display. These measurements can be used to assist the clinician in a cardiac evaluation.

Calcium Scoring

The Calcium Scoring software option for use with Ziostation is a non-invasive post processing software tool that can be used with CT images to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease.

Predicate Device

Ziosoft tool	Manufacturer of Predicate Device	Device Name	510(k) Number
Cardiac Function Analysis	Toshiba	CT Cardiac Function Analysis Software	K023760
Calcium Scoring	Toshiba	CSCS-001 A Calcium Scoring	K072737
	Voxar	Calcium Scoring	K020140

Device Description

Cardiac Function Analysis and Calcium Scoring are add-on software packages designed to be used with the basic Ziostation image management system to further aid clinicians in their analysis of anatomy and pathology. Universal functions such as data retrieval, storage, management, querying and listing, and output are handled by the basic Ziostation software. The additional capabilities provided by these two new devices are:

Cardiac Function Analysis

Cardiac Function Analysis software post-processes ECG-gated cardiac CT images and extracts the following left ventricular parameters from multi-phase data.

- Left ventricular ejection fraction
- End diastolic volume
- End systolic volume
- Stroke volume
- Cardiac output
- Cardiac Index
- Wall thickness
- Wall thickness ratio
- Wall movement
- Volume Curve

Calcium Scoring

Calcium Scoring software post-processes DICOM-based cardiac CT images and evaluates calcified plaque in the coronary arteries, providing the clinician with both Agatston and Volume calcium scores. These regions of interest are selected by the user.

Materials

The Cardiac Function Analysis and Calcium Scoring tools consist entirely of software. No materials are contained in this product.

Testing Summary

The Cardiac Function Analysis and Calcium Scoring software packages will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been addressed by a Risk Management process.

Summary of Substantial Equivalence

Cardiac Function Analysis and Calcium Scoring are substantially equivalent in intended use and function to their respective predicate devices and other devices already marketed in the US.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Ball
Director, Regulatory and Quality Affairs
Ziosoft, Inc.
1000 Bridge Parkway, Suite 100
REDWOOD CITY CA 94065-1186

MAR 31 2009

Re: K083446
Trade/Device Name: Cardiac Function Analysis and Calcium Scoring
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 25, 2009
Received: March 26, 2009

Dear Mr. Ball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083446

Device Name: Cardiac Function Analysis and Calcium Scoring

Indications for Use:

Cardiac Function Analysis

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083446